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FEB 28 2001

Ms. Eileen Vennum
Vice President, Regulatory Affairs
Mannatech, Inc.
600 S. Royal Lane
Suite 200
Coppell, Texas 75019

Dear Ms. Vennum:

This is in response to your letters of January 17, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Mannatech, Inc. is making the following claims, among others, for the following products:

Ambrotose Powder, Ambrotose capsules, and Ambrotose capsules with lecithin
“...delay the onset of various degenerative conditions”

Manna-C™ Capsules

“...can be used in conjunction with over-the-counter and prescription drugs taken to manage the symptoms of allergy”:
“Your simple allergic reaction may be a seasonal discomfort...”
“When sensitive people exposed to allergens...inflammation of the nasal and sinus passages...sneezing, itchy and watery eyes, coughing, wheezing and nasal congestion”
“...help in your seasonal discomfort from reactions”

MannaCleanse™ Capsules

“...inhibit growth of not-so-friendly micro-organisms. Potentially toxic bacteria can eventually cultivate in the colon if not competitively inhibited by good bacteria.”

AmbroStart Drink Mix

“Helps lower serum cholesterol levels in individuals with elevated cholesterol”
“Aids in the control of diabetes. Insulin-requiring diabetics often need lower amounts of insulin when they consume a diet high in soluble fiber”
“...prevent the growth of disease-producing bacteria...help alleviate lactose intolerance.”

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Page 2 - Ms. Eileen Vennum

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Your submission also states that Mannatech, Inc. is making claims that the product **AmbroStart Drink Mix** contains dietary fiber and that it may reduce the risk of some forms of cancer and cardiovascular disease.

These statements are claims of a relationship between dietary fiber and diseases, namely, cancer and cardiovascular disease. These statements are not claims subject to 21 U.S.C. 343(r)(6), but claims subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between soluble fiber from certain foods and the risk of coronary heart disease (see 21 CFR 101.81). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between soluble fiber and coronary heart disease. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.81 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.81 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, coronary heart disease. Your product does not appear to contain a fiber that would enable its label or labeling to bear the health claim authorized in 21 CFR 101.81. Moreover, FDA has not authorized a health claim for between soluble fiber and cancer and, therefore, the cancer prevention claims being made for this product appear to subject it to regulation as a drug under the Act.

Page 3 - Ms. Eileen Vennum

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Dallas District Office, Office of Compliance, HFR-SW140

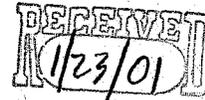
cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (r/f, file)
HFS-811 (file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Benz)
GCF-1 (Nickerson)
f/t:HFS-811:rjm:2/16/01:docname:74150.adv:disc54



January 17, 2001

Office of Special Nutritionals, (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street, S.W.
Washington, D.C. 20204



Re: Statements of Nutritional Support Notification for Ambrotose complex

Dear Sir or Madam:

In accordance with 21 U.S.C. 343(r)(6), Mannatech Incorporated, 600 S. Royal Lane, Suite 200, Coppell, Texas, 75019, hereby submits an original and two copies of it's notification for a dietary supplement product marketed prior to January 6, 2001.

Supplement Brand Name:

Ambrotose powder
Ambrotose capsules
Ambrotose capsules with lecithin.

Supplement Functional Ingredients: See attachment.

Statement of Nutritional Support:

Helps provide saccharides used in glycoconjugate synthesis

Included with this submission is text of product labeling for your review.

Mannatech Incorporated certifies that it possesses adequate substantiation for these statements of nutritional support; that the substantiation renders them truthful and non-misleading and thus permissible under the Dietary Supplement Health and Education Act (DSHEA); and that the information contained in this notice is complete and accurate.

Sincerely,

Eileen Vennum, RAC
Vice President, Regulatory Affairs

Enclosures: as described

Ambrotose® Powder

Arabinoglactan (<i>larix decidua</i>)
Rice Starch
Aloe vera extract (inner leaf gel) - Manapol® Powder
Ghatti (<i>Anogeissus latifolia</i>) (gum)
Glucosamine HCl
Tragacanth (<i>Astragalus gummifer</i>) (gum)

Ambrotose® Capsules

Arabinoglactan (<i>larix decidua</i>)
Rice Starch
Aloe vera extract (inner leaf gel) - Manapol® Powder
Ghatti (<i>Anogeissus latifolia</i>) (gum)
Tragacanth (<i>Astragalus gummifer</i>) (gum)

Feel the power of optimal cell-to-cell communication:

**No combination of vitamins,
minerals, amino acids or herbals
can replace the saccharides
found in this product.**

In August 1996, researchers at Mannatech Inc. took a giant step in securing a proprietary position in the rapidly changing, constantly expanding nutritional supplement industry with the filing of a new set of composition and use patent claims for a unique, nutritional supplement—Ambrotose® complex. This nutritional supplement provides raw materials for the body to use to promote optimal cellular communication. It is a glyconutrient, a blend of specific plant saccharides that provides support for the immune system. These saccharides are necessary for the body's creation of glycoforms, the structures on cell surfaces used to "talk" to other cells.

Saccharides show promise for more health benefits.

An increasing number of scientists believe that certain carbohydrates represent the next frontier in the search for non-toxic compounds that delay the onset of various degenerative conditions. Even though we have just begun to scratch the surface in understanding the full potential of these carbohydrates, the research being reported in just the last decade has ignited a new level of hope and cautious optimism with some of the world's leading immunologists.



Good communication between cells is necessary for:

- Supporting proper gland and organ function.
- Proper system function, including your natural defense and endocrine systems.
- Optimal health.

Ambrotose® complex

In an industry in which natural products have become the new national focus, no technology offers more promise than the discovery and use of certain carbohydrates. Some researchers call Ambrotose® complex the most important and exciting nutritional discovery in recent years.

#351—(60 capsules)
Retail \$39.00
Wholesale **\$28.50**

Ambrotose® complex with soy lecithin, a plant lipid designed to aid the absorption of certain monosaccharides.

#141—(60 capsules)
Retail \$39.00
Wholesale **\$28.50**

Ambrotose® in powder form without soy or rice flour. May be easily mixed with water, fruit or vegetable juice, or meals.

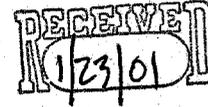
#371—(100 G.)
Retail \$125.00
Wholesale **\$100.00**

#372—(50 G.) 1/2 canister
Retail \$65.00
Wholesale **\$55.00**





January 17, 2001



Office of Special Nutritionals, (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street, S.W.
Washington, D.C. 20204

Re: Statements of Nutritional Support Notification for Manna-C™ Capsules

Dear Sir or Madam:

In accordance with 21 U.S.C. 343(r)(6), Mannatech Incorporated, 600 S. Royal Lane, Suite 200, Coppell, Texas, 75019, hereby submits an original and two copies of its notification for a dietary supplement product marketed prior to January 6, 2001.

Supplement Brand Name: Manna-C™ Capsules

Supplement Functional Ingredients: See attachment.

Statement of Nutritional Support:
Supports nasal and sinus health.

Included with this submission is text of product labeling for your review.

Mannatech Incorporated certifies that it possesses adequate substantiation for these statements of nutritional support; that the substantiation renders them truthful and non-misleading and thus permissible under the Dietary Supplement Health and Education Act (DSHEA); and that the information contained in this notice is complete and accurate.

Sincerely,

Eileen Vennum
Vice President, Regulatory Affairs

Enclosures: as described

Manna-C™

Vitamin C (from Acerola fruit)

Ambrotose® complex (patent pending) Naturally occurring plant polysaccharides including freeze-dried aloe vera inner leaf gel-extract - Manapol® powder

Herbal blend:

Boneset (aerial part), Lemon verbena (leaves), Sage (leaves), Catnip (aerial part), Peppermint (leaves), Yarrow (flowers), Horehound (aerial part)



Nutritional Cofactor

Vitamin C is a nutritional cofactor that supports many biological reactions, such as those that are involved in the regulation of histamine. Nutritional studies have shown that people who have marginal levels of vitamin C have increased blood levels of histamine and, conversely, cells with adequate levels of vitamin C tend to have reduced levels of histamine. Therefore, when histamine levels rise, the nutritional need for vitamin C may increase. Reduced histamine levels have been shown to be associated with optimal nasal and sinus health.

Shouldn't the world be a little less irritating?

Your simple allergic reaction may be a seasonal discomfort that occurs only once or twice a year. When sensitive people are exposed to allergens, their mast cells—the first line of defense of their immune systems—release histamine. This causes an all too familiar inflammation of the nasal and sinus passages, which can trigger sneezing, itchy and watery eyes, coughing, wheezing and nasal congestion.

Mannatech's Manna-C™ is here to support your nasal and sinus health, to help in your seasonal discomfort from reactions. Manna-C™ has been specifically designed to nutritionally support your body's natural ability to regulate histamine. The unique combination of Ambrotose® complex, an herbal blend and natural vitamin C is safe and effective, even when used daily.

Ambrotose® complex combines monosaccharides needed in the body's manufacture of glycoproteins with an herbal blend that yields natural sources of vitamin C and other nutrients that are utilized in support of mast cell function.

Manna-C™ also features a natural form of vitamin C from acerola, a wild cherry-like fruit that is considered one of nature's richest sources of this vitamin.

This special formulation also provides an herbal blend which includes lemon verbena, sage, peppermint and other herbs containing additional phytonutrients.



Manna-C™

Manna-C™ is designed to support nasal and sinus health by nutritionally supporting the body's natural ability to regulate histamine. It is safe and effective even when used daily and can be used in conjunction with over-the-counter and prescription drugs taken to manage the symptoms of allergy. It features Ambrotose® complex, an herbal blend, and a natural source of Vitamin C.

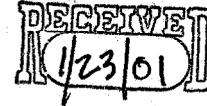
#391—(60 capsules)
Retail \$39.00
Wholesale **\$28.50**





January 17, 2001

Office of Special Nutritionals, (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street, S.W.
Washington, D.C. 20204



Re: Statements of Nutritional Support Notification for AmbroStart® Drink Mix

Dear Sir or Madam:

In accordance with 21 U.S.C. 343(r)(6), Mannatech Incorporated, 600 S. Royal Lane, Suite 200, Coppell, Texas, 75019, hereby submits an original and two copies of its notification for a dietary supplement product marketed prior to January 6, 2001.

Supplement Brand Name: AmbroStart Drink Mix

Supplement Functional Ingredients: See attachment

Statement of Nutritional Support:

Provides nutrients that can quickly be absorbed and converted into energy.
Provides Mannatech 2001 fiber, a fiber that has been found to stimulate the growth of beneficial bacteria in the gastrointestinal tract.

Included with this submission is text of product labeling for your review.

Mannatech Incorporated certifies that it possesses adequate substantiation for these statements of nutritional support; that the substantiation renders them truthful and non-misleading and thus permissible under the Dietary Supplement Health and Education Act (DSHEA); and that the information contained in this notice is complete and accurate.

Sincerely,


Eileen Venum, RAC
Vice President, Regulatory Affairs

Enclosures: as described

AmbroStart™

Fructose
Citric acid
Medium chain triglycerides
Calcium Citrate
Magnesium aspartate
Magnesium succinate
Potassium Aspartate
Potassium succinate
Choline bitartrate
Lecithin
Mannatech™ 2001 Fiber (Arabinogalactan)
Ambrotose® complex (patent pending) Naturally occurring plant polysaccharides including freeze-dried aloe vera inner leaf gel extract – Manapol® powder
Stevia extract (leaf)

Orange-flavored,
energy releasing,
fiber
enhancing.

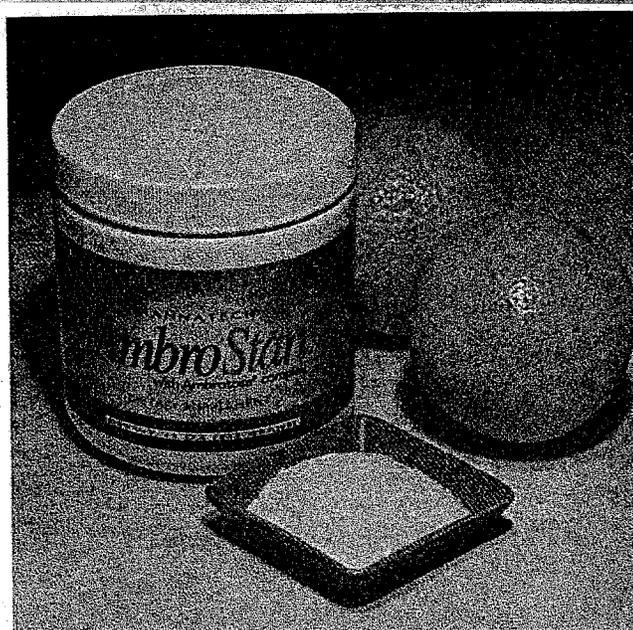
AmbroStart® beverage mix is a product specifically designed by Mannatech to provide nutrients that can quickly be absorbed and converted into energy. One of the main ingredients, fructose, is a carbohydrate that can energize without giving you that "let down feeling" typical of some sugars.

It is also formulated with medium chain triglycerides, another important source of energy. Additionally, AmbroStart® contains metabolic intermediates that enter the energy cycle directly without needing to be broken down. This enables the body to instantly use these compounds for energy production.

AmbroStart® also features Ambrotose® complex, the flagship ingredient of all Mannatech's dietary supplements, and Mannatech 2001 Fiber™, a new generation of soluble fiber that has been found to stimulate the growth of beneficial bacteria in the gastrointestinal tract. Maximum health benefits are positively correlated with the amount of fiber in the diet.

Dietary fiber is important in human nutrition. The National Cancer Institute recommends a high fiber, low fat diet to help prevent some forms of cancer. The same recommendation is made by the American Heart Association to help prevent cardiovascular disease. These are two of the leading causes of death in the United States.

The typical American diet contains between 10 to 15 grams of fiber daily. Even the most conservative nutritionists believe we need between 20 and 40 grams daily. Some believe that 40 to 50 grams of fiber would be even healthier. Most of us could benefit from dietary supplementation of soluble fiber.



Soluble fiber:

- Helps lower serum cholesterol levels in individuals with elevated cholesterol.
- Lowers the risk of colon and rectal cancer in populations that consume a mixed, high fiber diet. The bulk produced by soluble fiber may dilute cancer-causing substances that are present in our diets, thus reducing the risks of cancer.
- It aids in control of diabetes. Insulin-requiring diabetics often need lower amounts of insulin when they consume a diet high in soluble fiber.
- Aids in controlling obesity. Soluble fiber expands to give a feeling of fullness that helps decrease appetite and, therefore, helps with weight control.
- Acts as a prebiotic. A prebiotic is a substance that promotes the growth of healthful bacteria that inhabit the colon. These friendly bacteria prevent the growth of disease-producing bacteria, improve digestion, may help alleviate lactose intolerance, and enhance immune function.

AmbroStart®

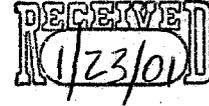


AmbroStart® mix makes a delicious orange-flavored beverage that helps you get your day off to a great start. Formulated to energize you, AmbroStart® beverage provides 3 grams of fiber per serving along with your daily regimen of necessary sugars from Ambrotose® complex. It can also be used as a pick-me-up beverage to help prevent that afternoon slump.

#350-(325 G.)
Retail \$65.00
Wholesale **\$55.00**



January 17, 2001



Office of Special Nutritionals, (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street, S.W.
Washington, D.C. 20204

Re: Statements of Nutritional Support Notification for MannaCleanse™ Capsules

Dear Sir or Madam:

In accordance with 21 U.S.C. 343(r)(6), Mannatech Incorporated, 600 S. Royal Lane, Suite 200, Coppell, Texas, 75019, hereby submits an original and two copies of its notification for a dietary supplement product marketed prior to January 6, 2001.

Supplement Brand Name: MannaCleanse™ Capsules

Supplement Functional Ingredients: See attachment.

Statement of Nutritional Support:

Designed to promote proper colon ecology and function.

Included with this submission is text of product labeling for your review.

Mannatech Incorporated certifies that it possesses adequate substantiation for these statements of nutritional support; that the substantiation renders them truthful and non-misleading and thus permissible under the Dietary Supplement Health and Education Act (DSHEA); and that the information contained in this notice is complete and accurate.

Sincerely,

Eileen Vennum, RAC
Vice President, Regulatory Affairs

Enclosures: as described

MANNACLEANSE™

Fiber Blend Oat fiber, black currant fiber, Psyllium (seed husk), carrageenan, glucomman
Essential oils & Botanical Blend Fenugreek (seed), fennel (seed), ginger (root), rosemary (leaves), neroli orange (blossom), peppermint (leaves).
Fatty Acid Blend Flax (seed), sodium caprylate, rice (bran), lecithin, borage (seed).
Flora Growth Promotants Inulin-oligosaccharide complex, Beta-glucans
Probiotic Flora <i>Lactobacillus sporogenes</i> , <i>L-axidophilus</i> , <i>L-plabtarium</i> , <i>L-casei</i> , <i>Bifidobacterium bifidum</i>
Enzyme Blend Amylase, protease, lactase, lipase, cellulase
Ambrotose® complex (patent pending) naturally occurring plant polysaccharides including freeze-dried aloe vera inner leaf gel extract-Manapol® powder.



Product designed to help support the body's lower digestive tract by:

- Supporting the natural ecology of the intestines
- Supporting the body's ability to fully break down food particles
- Supporting the body's ability to expel unused or unneeded material



MANNA•Cleanse™

MANNA•Cleanse™ caplets are a unique product, expressly developed for intestinal health. The formula combines natural fibers, herbs, oils, and probiotics which provide a healthy environment for the intestinal tract. Each ingredient was carefully chosen for its beneficial function in colon health.

MANNA•Cleanse caplets are to be taken, preferably with a full glass of water, between meals for maximum benefit and effectiveness.

#361-(120 capsules)
Retail \$39.00
Wholesale \$28.50

Get the most - out of your food and supplements

Each ingredient in MANNA•Cleanse™ has been carefully selected to support the natural health of the intestinal tract and its supporting systems.

Natural fibers

Necessary for proper colon function, fiber has long been recognized for its benefits as an intestinal cleanser, aiding peristalsis (muscular movement of the intestinal tract). Specifically, oat bran, psyllium, and plant cellulose were chosen to aid in removing substances from the colon.

Botanicals and oils

Essential to promote kidney, liver and spleen function. Selective herbs such as ginger root, rosemary, and peppermint were chosen for a calming effect on the intestinal tract.

Ambrotose® complex

The unique, proprietary blend of polysaccharides which are important for the membrane integrity of every cell in the body, as well as their functions in immune responsiveness and cellular communication.

Fatty acids

Meal from whole flax seed and borage seed is included in the formula because these foods are known to be good natural sources of omega-3 and omega-6 fatty acids. These are essential for rebuilding new cells, for nerve transmission, and for production of prostaglandins—hormone-like substances that act as chemical messengers and regulators of various body processes.

Digestive enzymes

Digestive enzymes greatly increase the breakdown of dietary starches, fats, and proteins.

Microflora

Essential as part of the normal ecology of the gastrointestinal tract to inhibit growth of not-so-friendly micro-organisms. Potentially toxic bacteria can eventually cultivate in the colon if not competitively inhibited by good bacteria.